IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant	: Freeman et al.	Art Unit	: 3766
Serial No.	: 10/786,359	Examiner	: Brian T. Gedeon
Filed	: February 24, 2004	Conf. No.	: 3423
Title	: USING CHEST VELOCITY TO PROCESS PHYSIOLOGICAL SIGNALS TO REMOVE CHEST COMPRESSION ARTIFACTS		

Mail Stop Appeal Brief - Patents
Commissioner for Patents
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BRIEF ON APPEAL

(1) Real Party in Interest

The real party in interest is ZOLL Medical Corporation, of Chelmsford, Massachusetts.

(2) Related Appeals and Interferences

There are no related appeals or interferences.

(3) Status of Claims

Claims 1, 2, 7-16, 19, 23, 26 and 28 stand rejected under 35 USC 102(b) as being anticipated by Halperin et al.

Claims 3-5 stand rejected under 35 USC 103(a) as being unpatentable over Halperin et al.

Claims 20-22 stand rejected under 35 USC 103(a) as being unpatentable over Halperin et al. in view of Haberl et al.

Claims 1-29 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 45-52 of U.S. Patent No. 7,220,235.

Claims 17, 18, 24, 25, 27, and 29 stand allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

(4) Status of Amendments

No amendments have been filed since the office action rejecting the claims.

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(5) Summary of Claimed Subject Matter

When a patient undergoes chest compressions (e.g., during CPR following cardiac arrest), it is desirable to acquire a physiological signal (e.g., an ECG signal showing cardiac activity) to determine what treatment to deliver (e.g., a defibrillation shock or continued CPR). But the chest compressions typically introduce signal artifacts in the physiological signal as a result of the compressions. Various efforts have been made to address these signal artifacts. One approach is to avoid using segments of the physiological signal taken during chest compressions; only "good" segments are analyzed. Another approach is to correct the physiological signal to reduce the artifact. The invention takes the latter approach.

The novelty of the invention is in the manner in which the signal artifact is reduced. Information on the velocity of chest compressions is determined, and the velocity information is used to reduce the signal artifact. Claim 1, the only independent claim, reads as follows:

> 1. (Original) A method of analyzing a physiological signal during application of chest compressions, the method comprising:
> acquiring a physiological signal during application of chest compressions;
> acquiring the output of a sensor from which information on the velocity of chest compressions can be determined; and
> using the information on the velocity to reduce at least one signal artifact in the physiological signal resulting from the chest compressions.

(6) Grounds of Rejection to be Reviewed on Appeal

The examiner's rejection of claim 1 under 35 USC 102(b) as being anticipated by Halperin is the ground of rejection to be reviewed on appeal. (The examiner also rejects claim 1 on double patenting grounds, but this is not an issue requiring appeal. It is expected that applicant can submit a terminal disclaimer that will satisfy the examiner.)

(7) Argument

As noted above, the novelty of claim 1 is the use of velocity information to reduce a signal artifact resulting from chest compressions. Claim 1 puts it this way:

using the information on the velocity to reduce at least one signal artifact in the physiological signal resulting from the chest compression.

There is absolutely no suggestion in Halperin of using velocity to reduce a signal artifact in a physiological signal, let alone reducing an artifact resulting from chest compressions. Thus, the examiner's rejection should be reversed.

Applicant pointed this out to the examiner in the reply to the first action:

> Halperin does teach deriving velocity from an acceleration measurement, but Halperin does not use the derived velocity to reduce an artifact in a physiological signal resulting from chest compression. Velocity is used for an entirely different purpose. As explained in the paragraph at col. 10, lines 30 to 37, velocity is used to determine angular displacements, which are used to compensate the acceleration signal to account for tilting of the sensors during use (Halperin suggests mounting the accelerometers on the rescuer's wrist, where their orientation can vary considerably).
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> The examiner lists column and line numbers for numerous sentences and paragraphs in Halperin where support can supposedly be found for the examiner's conclusion that Halperin teaches using velocity to reduce an artifact in a physiological signal. But in every instance, the examiner's referenced language teaches nothing of the kind. The only teaching in Halperin of how to reduce the physiological signal artifact is to use measured acceleration (e.g., col. 9, line 64 to col. 10, line 6; col. 12, lines 8-19).

The use to which Halperin puts the velocity information is altogether different from that required by the claim. Halperin wants to correct for tilting of the rescuer's hand – because the accelerometer is installed on the rescuer's hand, and thus tilt of the hand will introduce errors in the acceleration measurement. Gyro sensors (24, 25) provide velocity information, from which Halperin teaches that hand tilt can be derived, and used to correct the output of the accelerometer. That is the only use taught for velocity information in the entirety of Halperin.

Applicant was confident that pointing this out to the examiner would result in the anticipation rejection over Halperin being withdrawn. But that is not what happened. The examiner did not take applicant's argument seriously, and simply maintained the anticipation rejection over Halperin. The examiner gave his reasons as follows:

> In response to Applicant's argument that Halperin does not use the derived

> velocity to reduce an artifact in a physiological signal, Halperin describes a hand-held chest compression monitor 10 wherein ECG signal lines 56 may be coupled to, col 9 lines 4-8. Two gyros 24 and 25 are used to measure angular velocity. CPR induced artifact must be eliminated from the ECG signal in order to produce an accurate ECG recording. Velocity is an example of noise associated with CPR artifact, col 11 lines 50-58. <u>Therefore it would have been obvious</u> to one of ordinary skill in the art at the time the invention was made to filter out the noise associated with velocity of CPR compressions in order to achieve an intelligible and accurate ECG signal.

The examiner's rejection should be reversed for at least three reasons:

First, the rejection is based on anticipation by Halperin. What would have been obvious to one of ordinary skill is irrelevant.

Second, and more importantly, the examiner's reasoning for an obviousness rejection is not supported by the teaching of Halperin. The examiner indicates that "Velocity is an example of noise associated with CPR artifact, col. 11 lines 50-58. *** Therefore, it would have been obvious *** to filter out the noise associated with velocity of CPR compressions in order to achieve an intelligible and accurate ECG signal." The examiner has grossly distorted what Halperin teaches. The paragraph referenced (col. 11, lines 50-58) reads as follows:

> FIG. 12 shows several waveforms pertinent to the processing of a CPR-affected ECG signal. A first waveform a.sub.r represents a measurable signal which "represents" the CPR-induced artifact. That signal may comprise a force, acceleration, distance, velocity, motion, or vest signal, each of which represents some aspect of the CPR-induced artifact. In the illustrated embodiment, the signal a.sub.r comprises the acceleration signal produced by the accelerometer 12 of the device shown in FIG. 1.

Although the examiner does not refer to them, the following three paragraphs of Halperin are instructive:

> The next waveform is the measure ECG signal e.sub.m, measured during CPR. The following waveform a.sub.p is the predicted artifact. The last waveform e.sub.m ', is the processed measured ECG signal, which has been processed to remove the CPR-induced artifact. The processed measured ECG signal e.sub.m ' shown in FIG. 12 was produced using linear predictive filtering as will be described below.

> When a true ECG e and artifactual components a overlap in both time and frequency domains, it is still possible to distinguish the two if a separate signal that is correlated with the artifact is available. The system that gives rise to the measured ECG signal e.sub.m can be modeled as the sum of the true ECG e and an artifact waveform a. This model is shown in FIG. 13. The true CPR noise signal a is treated as the output of a linear system H perturbed by a measurable input a.sub.r.
>
> The goal of linear predictive filtering, in accordance with the embodiment disclosed herein, is to identify the linear system H that transforms the acceleration signal a.sub.r into the waveform composed of the artifactural components, i.e., a, in the measured ECG e.sub.m. Once this system is identified, the artifactual component can be predicted, using linear perdictive filtering, by taking the output a.sub.p of a simulated system H, using the acceleration signal a.sub.r as the input. When this linearly predicted signal ap is substracted from the measured ECG e.sub.m, the resulting signal is the estimated true ECG, which is shown as the processed ECG signal e.sub.m ' in the output of the system shown in FIG. 14.

The first paragraph (referred to by the examiner) indicates that the first signal in FIG. 12, which is named a_r, represents the CPR-induced artifact. What is actually shown is acceleration, but Halperin indicates that other signals could represent the artifact, including force, acceleration, distance, velocity, motion, or vest signal.

The examiner misunderstands what Halperin has written, and concludes that "Velocity is an example of noise associated with CPR artifact, col 11 lines 50-58." And then goes on to say that "Therefore it would have been obvious *** to filter out the noise associated with velocity of CPR compressions in order to achieve an intelligible and accurate ECG signal." This is not what Halperin teaches. Yes, Halperin is interested in removing the CPR artifact, but nowhere in Halperin is there any suggestion of "filter[ing] out the noise associated with velocity of CPR compressions" Indeed, as can be seen in the next three paragraphs, Halperin teaches the use of the acceleration signal to form a linearly predicted signal to remove the artifact.

Third, the examiner is confusing the velocity measured by Halperin with the mention of velocity in the paragraph at col. 11, lines 50-58. Halperin measures velocity using gyro sensors to correct for hand tilt (rotation of the hand instead of pure up and down movement). The mention of velocity in col. 11 is merely in passing as an indication that one could represent the CPR artifact using a variety of signals, including velocity. <u>Halperin is not saying in col. 11 that</u>

velocity information should be used to reduce the CPR artifact. There is no indication of this anywhere.

Accordingly, the rejection of claim 1 as anticipated by Halperin should be reversed.

The brief fee in the amount of $540 is being paid concurrently herewith on the Electronic Filing System (EFS) by way of Deposit Account authorization. Please apply any other charges or credits to Deposit Account No. 06-1050, referencing 04644-0156001.

Respectfully submitted,

Date: 6/22/2009

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Appendix of Claims

1. A method of analyzing a physiological signal during application of chest compressions, the method comprising:

acquiring a physiological signal during application of chest compressions;

acquiring the output of a sensor from which information on the velocity of chest compressions can be determined; and

using the information on the velocity to reduce at least one signal artifact in the physiological signal resulting from the chest compressions.

2. The method of claim 1 wherein the physiological signal is an ECG signal.

3. The method of claim 1 wherein the physiological signal is an IPG signal.

4. The method of claim 1 wherein the physiological signal is an ICG signal.

5. The method of claim 1 wherein the physiological signal is a pulse oximetry signal.

7. The method of claim 1 or 2 wherein the sensor is a velocity sensor, and the information on the velocity is determined from the velocity sensor.

8. The method of claim 1 or 2 wherein the sensor is an accelerometer, and the information on the velocity is determined from integration of the output of the accelerometer.

9. The method of claim 1 or 2 wherein using the information on the velocity to reduce at least one signal artifact in the physiological signal comprises time aligning the physiological signal with the velocity.

10. The method of claim 1 or 2 wherein using the information on the velocity to reduce at least one signal artifact in the physiological signal comprises using an adaptive filter that is adjusted to remove chest compression artifacts.

11. The method of claim 1 or 2 further comprising a ventricular fibrillation detection algorithm for processing the physiological signal with reduced artifact to estimate whether a ventricular fibrillation is present.

12. The method of claim 10 further comprising a preprocessing step that detects when chest compressions are applied and automatically initiates the adaptive filter.

13. The method of claim 11 further comprising enabling delivery of a defibrillation shock if the algorithm estimates that ventricular fibrillation is present.

14. The method of claim 10 wherein a difference signal is produced, the difference signal being representative of the difference between the physiological signal fed into the adaptive filter and the physiological signal after artifact reduction by the adaptive filter.

15. The method of claim 14 wherein the difference signal provides a measure of the amount of artifact in the physiological signal.

16. The method of claim 15 further comprising the step of using the difference signal to modify the subsequent processing of the physiological signal.

17. The method of claim 16 wherein, if the difference signal indicates that the amount of artifact exceeds a first threshold, the ventricular fibrillation detection algorithm is modified to make it more resistant to being influenced by the artifact.

18. The method of claim 17 wherein, if the difference signal indicates that the amount of artifact exceeds a second threshold higher than the first threshold, use of the ventricular defibrillation detection algorithm is suspended.

19. The method of claim 16 wherein spectral analysis is performed on the difference signal, and adjustments are made to filtering of the physiological signal based on the outcome of the spectral analysis.

20. The method of claim 10 wherein the velocity signal undergoes a normalization pre-processing prior to being fed to an adaptive filter

21. The method of claim 10 wherein the adaptive filter comprises an FIR filter.

22. The method of claim 21 wherein the adaptive filter comprises a zero-th order filter.

23. The method of claim 10 wherein the adaptive filter comprises coefficients that are dynamically controlled by an estimate of the physiological signal.

24. The method of claim 10 wherein the adaptive filter comprises the capability of being automatically reset when the difference between the filter output and the measured physiological signal is beyond a threshold.

25. The method of claim 24 wherein the automatic reset comprises the capability of dynamically changing the step size and thus improving the relationship of convergence and stability of the filter.

26. The method of claim 1 or 2 further comprising a time-aligning process performed on the physiological and velocity signals, wherein the time aligning process aligns the two signals relative to the compressions.

27. The method of claim 26 further comprising adaptive filtering of the output of the time aligning process, wherein the adaptive filtering reduces the error between the physiological and velocity signals.

28. The method of claim 10 wherein the adaptive filter comprises a Kalman filter.

29. The method of claim 10 wherein the adaptive filter employs adaptive equalization.

Evidence Appendix

NONE.

Related Proceedings Appendix

NONE.